

September 8, 2008

**SUBMITTED VIA ELECTRONIC MAIL**

Judy Lombardo  
IDEM Office of Air Quality  
100 North Senate Avenue,  
MC 61-53, IGC-N 1003  
Indianapolis, IN 46205

**RE: Comments of Eli Lilly and Company on Proposed revisions to Non-Rule Policy Document Air-007-NPD-R2**

Eli Lilly and Company ["Lilly"], appreciates the opportunity to comment on the proposed revisions to IDEM's non-rule policy document on Title V and FESOP annual compliance certifications [Air-007-NPD-R2]. Lilly supports IDEM's proposal because it will satisfy the requirements of the Title V operating permit program and provides IDEM and the public with the most useful information regarding a source's compliance status.

By enabling and encouraging sources to utilize the so-called "short-form" version of an annual compliance certification, the revised non-rule policy document ensures that sources will prepare and submit their annual compliance certifications in the most cost-effective manner. Moreover, the policy drives the focus of the compliance certifications towards communicating the most important compliance-related information instead of burdening the system with details about every single requirement in the Title V permit or FESOP. It was this philosophy that caused USEPA's Title V Performance Task Force to recommend using short-form compliance certifications, and we are pleased that IDEM has decided to follow the Task Force's recommendation.

Although we strongly support the concept of the short-form ACC and the revised non-rule policy document, Lilly would like to offer some additional revisions to the document. Our comments are intended to improve the document by ensuring that the language in the document is consistent with applicable rules, and to make the language more clearly state the expectations of IDEM. For example, we found a few instances where the language in the document and form was confusing or inconsistent.

In particular, Lilly believes that the annual compliance certification form should not be used to require information about individual deviations that may have occurred during the reporting period. As currently written, the form includes two columns relating to

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information about individual deviation events. That kind of information is reported in quarterly deviation reports or other compliance reports, not in an annual compliance certification. For the compliance certification, a source is required to identify its compliance status during the reporting period as it relates to the permit terms. The certification should not be used to collect information about individual deviation events.

We understand that IDEM has provided these columns so that a source may provide information about deviations if a source failed to report a deviation during a quarterly report or other compliance report. Instead of using the compliance certification form to gather information about these events, Lilly recommends that IDEM have sources provide the necessary information on a quarterly deviation reporting form or a form that meets the content requirements of deviation reports.

This approach will preserve the distinction between deviation reports and compliance certifications.

In addition to comments that reflect this concern, Lilly has other comments that will improve a source's ability to understand and follow the non-rule policy document. Are comments are noted in the attached red-lined versions of the proposed document and the certification form.


If you have questions, please contact me at 317-276-0331 or by e-mail at bpaul@lilly.com.

Sincerely,

A handwritten signature in black ink that reads "B. Paul". The letters are cursive and fluid, with a large "B" and a stylized "Paul".

Bernard Paul

Attachments: Red-lined Proposed policy Air-007-NPD-R2  
Red-lined sample annual compliance certification form

<b>INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT</b>	<b>STATUS:</b> Active	<b>POLICY NUMBER:</b> AIR-007-NPD-R2	
<b>AGENCY NONRULE POLICY DOCUMENT</b>	<b>AUTHORIZED:</b> Daniel Murray, Assistant Commissioner, Office of Air Quality; and Phil Perry, Branch Chief, Compliance Branch, Office of Air Quality		
	<b>SUPERSEDES:</b> AIR 007 NPD AIR 007 NPD R1	<b>ISSUING OFFICE(S):</b> Office of Air Quality, Compliance Branch	
	<b>ORIGINALLY EFFECTIVE:</b> March 6, 1997	<b>RENEWED/REVISED:</b> September 6, 2002 April 1, 2008	
<b>SUBJECT:</b> Guidelines for Submittal and Review of Annual Compliance Certifications under the Federally Enforceable State Operating Permit (FESOP) and Part 70 Permit Programs			

**Disclaimer:** This Nonrule Policy Document (NPD) is intended solely as guidance and does not have the effect of law or represent formal Indiana Department of Environmental Management (IDEM) decisions or final actions. This nonrule policy document shall be used in conjunction with applicable laws. It does not replace applicable laws, and if it conflicts with these laws, the laws shall control. This nonrule policy document may be put into effect by IDEM thirty (30) days after presentation to the appropriate State Environmental Board. Pursuant to IC 13-14-1-11.5, this policy will be available for public inspection for at least forty-five (45) days prior to presentation to the appropriate board. If the nonrule policy is presented to more than one State Environmental Board, it will be effective thirty (30) days after presentation to the last board. IDEM will submit the policy to the Indiana Register for publication. Revisions to the policy will follow the same procedure of presentation to the State Environmental Board and publication.

## 1. PURPOSE

Guidelines for IDEM FESOP and Part 70 permittees for the annual compliance certification submittal and review requirements under 326 IAC 2-7-5, 326 IAC 2-7-6(5)(C) and 326 IAC 2-8-5(a)(1)(C).

## 2. SCOPE

IDEM will begin using this revised nonrule policy document in reviewing annual compliance certifications submitted after the effective date of this nonrule policy until such time as the nonrule policy document is revised.

## 3. SUMMARY

This Nonrule Policy Document outlines the procedures for the FESOP and Part 70 permittees for the annual compliance certification submittal and review requirements under 326 IAC 2-7-5, 326 IAC 2-7-6(5)(C) and 326 IAC 2-8-5(a)(1)(C).

## 4. DEFINITIONS

**"Authorized Individual"** ~~As defined in For FESOP requirements Pursuant to~~ 326 IAC 2-1.1-1(1). "Authorized individual" means an individual responsible for the overall operation of one (1) or more manufacturing, production, or operating plants or a duly authorized representative of such person. For any public agency, the term means either a ranking elected official, the chief executive officer, or a designated representative of such person having responsibility for the overall operations of a principal geographic unit of the agency. The definition of an "authorized individual" is similar to that of a "responsible official", except that the definition of authorized individual is not as narrow. IDEM expects that the authorized individual would have a similar level of control as a responsible official, but the definition could include health and safety managers and others.

**"Continuous compliance (CC)"** ~~In order to certify continuous~~The compliance ~~status, when~~ a source ~~must have~~has no deviations, irrespective of the monitoring frequency, for the relevant

permit term or condition during the reporting period. If a source has identified a deviation during the reporting period, a source cannot certify continuous compliance for the relevant permit term or condition.

**“Deviation”** - An exceedance of a permit limitation or a failure to comply with a requirement of the permit, including exceedances during an emergency. Deviations ~~would include exceeding a permit limitation for a specified pollutant, or not taking failing to take~~ a required action, such as the failure to conduct specified compliance monitoring, ~~to failure to~~ take a response step, or ~~failure to~~ maintain proper records, ~~or exceeding a permit limitation for a specified pollutant. For each of the terms and conditions, that had deviations, the source should provide the information called for in the table. In any case, the source should review the permit terms and conditions carefully when completing the annual compliance certification to make sure the certification is accurate and addresses each relevant permit term and condition. It should be noted that the identification of a deviation does not mean an enforcement action will be initiated. A determination of whether an enforcement action will be initiated can only be made after review and analysis of the data collected from the required monitoring, reports of deviations and any other credible evidence.~~

**Comment [BP1]:** This language should be deleted because it contains instructions about completing the compliance certification and goes beyond the scope of the definition of “deviation”. Instructional language such as this should be included elsewhere in the NPD.

**“Intermittent Compliance (IC)”** – ~~The compliance status when a source has determined that a deviation for the relevant permit term or condition has occurred during part or all of the reporting period. The time during the reporting period where there was a deviation. If a deviation has occurred during the reporting period, the source must certify intermittent compliance for the particular permit term or condition. The source must provide information about the deviation, including what the deviation was, how long the deviation lasted, estimates of excess emissions, whether or not the deviation was corrected, and the actions taken to correct the deviation.~~

~~o If this information has been submitted to IDEM previously in a Quarterly Deviation and Compliance Monitoring Report or other required report, then the source should provide the date of that report in the column:~~

~~o If this information has not been submitted previously, then the source should attach the information to the certification and the date included in the “Report date/Comments” column would be the date of the certification.~~

~~It should be noted that the identification of a deviation does not mean an enforcement action will be initiated. A determination of whether an enforcement action will be initiated can only be made after review and analysis of the data collected from the required monitoring, reports of deviations and any other credible evidence.~~

**Formatted:** Bullets and Numbering

**“Methods”** - One of the items that is required as part of an annual compliance certification is the identification of the “methods or means” used to determine the compliance status with each permit term or condition. The following is a list of standard monitoring methods and abbreviations that may be used to complete the annual compliance certification.

- o Continuous emission monitoring system = CEMS
- o Continuous opacity monitoring system = COMS
- o Stack test = ST
- o Visible emissions = VE
- o Record keeping = RK
- o Review of records = RR
- o Mass balance = MB
- o Emission factors = EF
- o Inspections = Insp
- o Fuel analysis = FA
- o Work practice = WP
- o Parametric monitoring = PM
- o Calculations = Calc
- o Other = O (specify in the Comments column)

**Comment [BP2]:** This language should be deleted because it contains instructions about completing the compliance certification and goes beyond the scope of the definition of “intermittent compliance”. Instructional language such as this should be included elsewhere in the NPD.

**“Responsible official”** - ~~As defined in For Part 70 requirements Pursuant to~~ 326 IAC 2-7-1(34)  
“Responsible official” means the following:

- A) For a corporation:
  - (i) a president;
  - (ii) a secretary;

- (iii) a treasurer;
- (iv) a vice president of the corporation in charge of a principal business function;
- (v) any other person who performs similar policy or decision making functions for the corporation; or
- (vi) a duly authorized representative of any person listed in this clause if the representative is responsible for the overall operation of one (1) or more manufacturing, production, or operating facilities applying for or subject to a Part 70 permit and either:
  - (AA) the facilities employ more than two hundred fifty (250) persons or have gross annual sales or expenditures exceeding twenty-five million dollars (\$25,000,000) (in second quarter 1980 dollars); or
  - (BB) the delegation of authority to such representative is approved in advance by the commissioner.

(B) For a partnership or sole proprietorship: a general partner or the proprietor, respectively.

(C) For a municipality, state, federal, or other public agency: either a principal executive officer or ranking elected official. As used in this clause, "principal executive officer of a federal agency" includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency, for example, a regional administrator of the U.S. EPA.

(D) For affected sources:

- (i) The designated representative for actions, standards, requirements, or prohibitions under Title IV of the CAA or the regulations promulgated there under; and
- (ii) The designated representative for any other purposes under a Part 70 permit.

An example of a responsible official or duly authorized representative would be a plant or site manager that is responsible for the overall operation of a manufacturing plant. Examples of individuals that do not meet the criteria include environmental consultants or environmental managers, human resource directors and safety coordinators that are not responsible for the overall operation of a plant.

## 5. ROLES

### Non-IDEM parties

"Authorized Individual"— Certifies any documents (including reports) where required by a FESOP permit.

"Responsible Official" – Certifies any documents, including reports, where required by a Part 70 permit.

**Comment [BP3]:** Not all documents required by a FESOP or Title V permit require certification by the authorized individual or responsible official.

## 6. POLICY

### General Requirements

- A. -The Annual Compliance Certification (ACC) must be submitted by the date identified in the permit as follows:
  - Part 70 (Title V) sources must submit the ACC to IDEM, U.S. EPA, Region 5, and the local air pollution control agency, where appropriate.
  - FESOP sources must submit the ACC to IDEM and the local air pollution control agency, where appropriate.

The submittal dates are April 15 or July 1 and the ACC must be postmarked, have a shipping date on a sender's receipt from a common carrier, or be hand delivered as of these dates. Refer to the permit to determine the specific submittal date and addresses.

- B. The Annual Compliance Certification must cover the period from January 1 through December 31 of the year being reported, except for the ~~first initial~~ year of the permit. For the ~~first initial~~ year of the permit, the certification is to cover the period from the date the permit becomes effective until December 31 of that same year the permit became effective. The time period the ACC covers should be noted on the certification.
- C. The Annual Compliance Certification must be signed by a responsible official as defined in 326 IAC 2-7-1(34) for Part 70 sources or authorized individual as defined in 326 IAC 2-1.1-1 for FESOP sources (See the Definitions section in this document); or must include the Part 70 or FESOP Certification Form that is in your permit. The certification on the ACC submitted to IDEM must contain an original signature and date.
- D. The Annual Compliance Certification report is to include the following:
  - o Identification of whether compliance during the period was continuous or intermittent (See Definitions, and Sample page 1, check box (17)).
  - o In cases where there was not continuous compliance with all permit terms and conditions, the identification of each ~~period-term or condition for which compliance was~~ intermittent ~~compliance~~.
  - o The identification of the method(s) or other means used by the owner or operator for determining the compliance status with each deviation during the certification period.
  - o Such other facts as the permitting authority may require in order to determine the compliance status of the source.
- E. Included with this nonrule policy document is a sample ACC form and guidelines for completion. Sources may create their own equivalent form for submittal as long as the required information outlined in this nonrule policy document and in applicable state and federal rules is included.

#### Permit amendments/modifications

The certification should be based on the source's compliance with all permit terms that existed during the reporting period, including those permit terms that were added, modified or deleted during the reporting period. Sources should be sure to review and use the most recent permit in effect during the reporting period as a starting point. The source should also review requirements replaced by permit amendments or permit modifications to determine if some requirements that require certification were in effect for a portion of the reporting period.

#### Permit renewals

Sources may need to address permit renewals where the new permit is issued at some point during the year. Sources should be sure to review the original permit and renewed permit that is in effect during the reporting period as a starting point. Compliance with respect to both the original permit and the renewed permit issued during the reporting period must be described in the ACC in a manner similar to that described above for permit amendments and modifications.

The ACC should be based on both permits that were in effect during the ACC reporting period and any intermittent compliance from those permits should be included in the ACC. In some cases, the source may wish to consult with IDEM about the proper way to address source specific situations.

#### Transfer of ownership and ACCs

In a situation where an owner transfers ownership or sells a source after December 31<sup>st</sup>, but prior to the ACC submittal deadline, IDEM suggests that the company buying the source require the seller to complete and submit the ACC prior to the sale, or at least, make sure the necessary information is available so the buyer can submit the ACC by the ACC submittal deadline. However, if the seller does not submit the ACC, the new owner would need to make the submission.

If a sale takes place after the submittal deadline or later in the year, the new owner will be responsible for submitting the ACC the following year. It is recommended that the new owner obtains the necessary information from the prior owner so that the ACC can be completed after the end of the year.

#### ACC Example

A completed example is attached at the end of the nonrule policy document. The example is included to show how the required information can be provided on the example ACC form to satisfy the annual compliance certification requirements. Each permit is different and each certification will be different because of the unique terms and conditions of the various permits.

#### Instructions for completing the ACC sample form

##### Source Information

- (1) Source Name: Enter the name of the source for the time period covered by the ACC.
- (2) Source Address: Enter the source's location address.
- (3) City: Enter the city where the source is physically located.
- (4) State: IN
- (5) Zip Code: Enter the zip code for the physical address of the source.
- (6) Mailing Address: If different from the location address, enter it here. Otherwise, leave blank.
- (7) Mailing City: If different from the location city, enter it here. Otherwise, leave blank.
- (8) Mailing State: If different from the location state, enter it here. Otherwise, leave blank.
- (9) Mailing Zip Code: If different from the location zip code, enter it here. Otherwise, leave blank.
- (10) Permit number: The 14 or 15 digit identification number for your Part 70 or FESOP permit. Include all permits, renewed permits, permit amendments, permit modifications that were in effect during the review period. Additional space is included in section (16) Comments if needed.
- (11) Reporting Period: The time period covered by this annual compliance certification. Generally, this would be January 1, to December 31, of the previous calendar year.
- (12) Contact Person: The person IDEM can contact if they have questions about information provided on this ACC. When completing this section, provide the name, phone number, etc. for the source contact person. This person should be someone that is familiar with the plant and the Part 70 or FESOP permit. This may be an environmental manager or a consultant, but does not have to be the same person signing the certification.
- (13) Email Address: The contact person's email address.
- (14) Phone Number: The contact person's phone number.
- (15) Fax Number: The contact person's fax number.
- (16) Comments: May provide any additional comments. For example, if the owner or operator has submitted an administrative amendment or minor permit modification, but IDEM has not acted on the application, it is suggested that the date the application was submitted be noted here.

##### Source Compliance Information

- (17) CHECK THE BOX NEXT TO EITHER (A) OR (B) ~~BELOW~~: Review compliance with each term and condition of your permit(s). Review the definitions of Continuous Compliance and Intermittent Compliance in the Definitions section of this document. Then certify compliance by checking the box next to either statement (A) or statement (B).
- (18) ~~LIST OF PERMIT~~ TERMS FOR WHICH THERE ~~IS WAS~~ INTERMITTENT COMPLIANCE: If the box next to statement (17)(B) is checked, identify all permit terms for which intermittent compliance occurred during the ~~time-reporting~~ period for this ACC. This table can be used to identify the terms and conditions in Sections B, C and D of your permit(s) ~~that had for which~~ deviations occurred during the reporting period ~~for which you are submitting the ACC~~. The Part 70 or FESOP permit Table of Contents can be used as a guide to include the condition number and description on the forms. It is not necessary to include the complete term or condition (see example).

There are some permit terms and conditions in Sections B and C whose compliance status ~~that~~ may be ~~inter~~dependent upon other terms and conditions in Sections D, E, etc. A source may clarify that intermittent compliance is associated with more than one permit term or condition by.

~~The associated permit term or condition may cross reference the other term(s) or condition(s) in the "Report date/Comments" column.~~

For deviations or emergency occurrences that occurred during the reporting period for this ACC, but were not previously reported in a deviation, emergency occurrence, quarterly or other compliance report, additional information should be attached to ~~the certification to describe the deviation, how long the deviation lasted, estimates of excess emissions, whether or not the deviation was corrected, and the actions taken to correct the deviation~~ provide the information ordinarily required by deviation and emergency reporting requirements. ~~A copy~~An attachment in the format of the Quarterly Deviation and Compliance Monitoring Report can be used to provide the ~~above~~ information regarding previously unreported deviations or emergencies. If the deviation or emergency was reported previously, ~~all that needs to be included is the date of the report in the "Report date/Comments" column~~ should include a reference to the date of the report that includes the information about the events.

**Permit Term/Condition:** For example D.1.10

**Description of Permit Condition:** You can use the description in your permit for this term or condition.

~~**Deviation Start Date:** The date the deviation of the stated condition began. If not previously reported:~~

~~**Deviation End Date:** The date the deviation of the stated ended. If not previously reported:~~

**Method Codes:** The methods by which compliance was determined. See the end of the Sample form or the Definitions section below for the list of codes.

**Report Date/Comments:** The owner operator should identify where/more detailed information about the deviations that led to the intermittent compliance can be found, such as date and type of the periodic report a deviation was previously reported on. (Ex. Quarterly Report, 1/1/07).

~~It should be noted that the identification of a deviation does not mean an enforcement action will be initiated. A determination of whether an enforcement action will be initiated can only be made after review and analysis of the data collected from the required monitoring, reports of deviations and any other credible evidence.~~

**Comment [BP4]:** These elements should be deleted from the form. Their presence leaves an implication that information about all deviations should be provided in the report, regardless of whether the deviation had been reported previously. Lilly believes that IDEM should emphasize to sources that they attach a report using the format of the Quarterly Deviation report.

**Comment [BP5]:** This language was moved from the definition of "deviation".

#### Signature Block for Certification

The Responsible Official or Authorized Individual as defined in the Definitions section of this document must sign and complete this section. A Responsible Official must sign the ACC for Part 70 or Title V sources. An Authorized Individual must sign the ACC for FESOP sources.

## 7. REFERENCES

Citations Affected: 326 IAC 2-7-5, 326 IAC 2-7-6(5)(C) and 326 IAC 2-8-5(a)(1)(C).

## 8. SIGNATURES

*Consistent with Part 6.1.7. of the Agency Policy, SOP, and QAPP Documentation Policy: The policy shall be authorized by the appropriate tiers of management, and "shall include a signature line for the Agency QA Manager(s) to signify the policy meets Agency format standards."*

\_\_\_\_\_  
Thomas W. Easterly, Commissioner,  
Indiana Department of Environmental Management

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Date

\_\_\_\_\_  
Daniel Murray, Assistant Commissioner,  
Office of Air Quality

\_\_\_\_\_  
Date

\_\_\_\_\_  
Robert Keene, Assistant Commissioner,  
Office of Legal Counsel

\_\_\_\_\_  
Date

\_\_\_\_\_  
Phil Perry, Branch Chief  
Compliance Branch  
Office of Air Quality

\_\_\_\_\_  
Date

This policy is consistent with Agency requirements.

\_\_\_\_\_  
Indiana Department of Environmental Management  
Quality Assurance Program  
Planning and Assessment

\_\_\_\_\_  
Date

## SAMPLE

### PART 70 / FESOP PERMIT- ANNUAL COMPLIANCE CERTIFICATION

This form can be used to satisfy the annual compliance certification requirements for Part 70 sources under 326 IAC 2-7-5, 326 IAC 2-7-6(5)(C) and FESOP sources under 326 IAC 2-8-5(a)(1)(C).

SOURCE INFORMATION					
(1) Source name:					
(2) Source address:					
(3) City:		(4) State:		(5) Zip code:	
(6) Mailing address: (if different from above)					
(7) Mailing City:		(8) Mailing State:		(9) Mailing Zip code:	
(10) Permit numbers:					
(12) Contact person:					
(14) Phone number:					
(16) Comments:					

SOURCE COMPLIANCE INFORMATION	
(17) CHECK THE BOX NEXT TO EITHER (A) OR (B) BELOW. (The terms "continuous compliance" and "intermittent compliance" are defined on the Definitions page).	
(A) This source was in <b>CONTINUOUS COMPLIANCE</b> with <b>all of the permit terms and conditions</b> that impose a work practice or emission standard or requires performance testing, monitoring, record keeping or reporting based on the monitoring methods in the permit.	
(B) This source was in <b>CONTINUOUS COMPLIANCE</b> with <b>all of the permit terms and conditions</b> that impose a work practice or emission standard or requires performance testing, monitoring, record keeping or reporting based on the monitoring methods in the permit, <b>except</b> for the terms and conditions listed in the following table for which the source reported intermittent compliance.	
<b>IMPORTANT:</b> If you select option (B), you must complete the following table in which you list any permit terms for which compliance was intermittent during the permit for the reporting period covered by this Compliance Certification.	

**(18) PERMIT TERMS FOR WHICH COMPLIANCE WAS INTERMITTENT**

[illegible]

**(18) PERMIT TERMS FOR WHICH COMPLIANCE WAS INTERMITTENT (Continued) – Attach additional sheets if necessary**

<b>Source Name:</b>					<b>Source Permit Number:</b>
<b>Permit Term/Condition</b>	<b>Description of Permit Condition</b>	<b>Deviation Start Date</b>	<b>Deviation End Date</b>	<b>*Method Codes</b>	<b>Report Date/Comments</b>

**\*Method Codes:**

Monitoring methods: CEMS = continuous emissions monitoring system; COMS = continuous opacity monitoring system; ST = stack test; VE = visible emissions; RK = record keeping; RR = review of records; MB = mass balance; EF = emissions factor; Insp = inspections; FA = fuel analysis; WP = work practice; PM = parametric monitoring; Calc = calculations; O = other (specify in Comments)

**For Part 70 sources:** The submittal by the Permittee requires the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

**For FESOP sources:** The notification which shall be submitted by the Permittee requires the certification by the “authorized individual” as defined by 326 IAC 2-1.1-1(1).

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.			
Signature:		Title/Position:	
Printed Name:		Date:	
Phone number:		Email Address:	

**PLEASE NOTE: YOU MUST EITHER SIGN THIS FORM OR ATTACH THE CERTIFICATION FORM INCLUDED IN YOUR PERMIT.**